# 510(k) Summary

SEP 19 2012

Summary of 510(k) Safety and Effectiveness

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| **Submitted By:** | Lucero Medical, LLC<br>P.O. Box 67<br>Richfield, OH 44286 |
| **Date:** | August 24, 2012 |
| **Contact Person:** | Jennifer Palinchik<br>Development and Regulatory Consultant |
| **Contact Telephone:** | (440) 933-8850 |
| **Device Trade Name:** | ENDURAMESH |
| **Device Classification Name:** | Spinal intervertebral body fixation orthosis |
| **Device Classification:** | Class II |
| **Reviewing Panel:** | Orthopedic |
| **Regulation Number:** | 888.3060 |
| **Product Code:** | MQP |
| **Predicate Device:** | Lucero Medical, LLC ENDURAMESH (K093207) |

**Device Description:**

The ENDURAMESH is a vertebral body replacement system which provides structural support of the vertebral bodies following an anterior or far lateral corpectomy, aiding in spinal fusion. The device must be used with a cleared supplemental fixation system.

The EDURAMESH vertebral body replacement system consists of a single cylindrically shaped titanium mesh cage. The hollow core of the cage allows for packing bone graft and the circular holes throughout the device promote bone fusions. Various diameters and heights are available to accommodate variability among patients.

**Indications for Use:**

The ENDURAMESH is a vertebral body replacement system intended for use in the thoracic and lumbar spine (T1-S1) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma/fracture. The device is intended for use with either allograft or autograft. The device must be used with a cleared supplemental fixation system.

**Substantial Equivalence Information:**

The design features, material, and indications for use of the ENDURAMESH system are substantially equivalent to the predicate device listed above. The safety and effectiveness is adequately supported by the substantial equivalence, material information, and analysis data provided within this Premarket Notification.

Predicate Comparison Chart:

| Item | ENDURAMESH | Modified ENDURAMESH |
|---|---|---|
| Product Code | MQP | MQP |
| Classification Name | Spinal intervertebral body fixation orthosis | Same |
| Intended Use | for use in the thoracic and lumbar spine (T1-S1) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma/fracture. | Same |
| Diameter | 13mm | Same |
| Height | 7mm-33mm (2mm increments), 41mm-53mm (2mm increments), 90mm | Same, plus 35mm, 37mm, 39mm |
| Material | Titanium Alloy | Same |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Lucero Medical, LLC
% Ms. Jennifer Palinchik
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SEP 19 2012

Re: K122622
Trade/Device Name: ENDURAMESH
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: August 24, 2012
Received: August 28, 2012

Dear Ms. Palinchik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K122622

Device Name: ENDURAMESH

**Indications for Use:**

The ENDURAMESH is a vertebral body replacement system intended for use in the thoracic and lumbar spine (T1-S1) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma/fracture. The device is intended for use with either allograft or autograft. The device must be used with a cleared supplemental fixation system.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122622